



Docket No.: CHR-004  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Norman R. Wainwright et al.

Application No.: 10/803,177

Confirmation No.: 4155

Filed: March 17, 2004

Art Unit: 1744

For: METHODS AND COMPOSITIONS FOR  
THE DETECTION OF MICROBIAL  
CONTAMINANTS

Examiner: N. A. Bowers

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (SIDS)**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom. The publication for corresponding International Patent Application PCT/US04/08013 is cited under B5. The published Search Report for this International Patent Application was previously cited to the Office under C72.

This Information Disclosure Statement is filed more than three months after the U.S. filing date, OR more than three months after the date of entry of the national stage of a PCT application, AND after the mailing date of the first Office Action on the merits, whichever occurs first, but before the mailing date of a Final Office Action or Notice of Allowance (37 CFR 1.97(c)).

In accordance with 37 CFR 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. Applicant submits herewith copies of foreign patents and non-patent literature in accordance with 37 CFR 1.98(a)(2).

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

Our check including the \$180.00 fee set forth in 37 CFR 1.17(p) is enclosed. The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 07-1700, under Order No. CHR-004. A duplicate copy of this paper is enclosed.

Dated: February 5, 2007

Respectfully submitted,

*Randall D. Moir Reg No. 58,312*

By *for*

Duncan A. Greenhalgh

Registration No.: 38,678

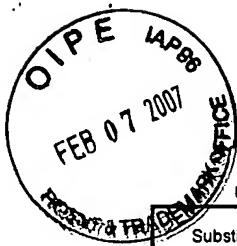
GOODWIN PROCTER LLP

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Boston, Massachusetts 02109

(617) 570-1000

Attorney for Applicant



PTO/SB/08A/B (09-06)

Approved for use through 03/31/2007. OMB 0651-0031

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet	1	of	1	Attorney Docket Number	CHR-004
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**Complete if Known**

Application Number	10/803,177
Filing Date	March 17, 2004
First Named Inventor	Norman R. Wainwright
Art Unit	1744
Examiner Name	N. A. Bowers
Attorney Docket Number	CHR-004

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1*	US-20030104501-A1	06-05-2003	Jordan et al.	
	A2*	US-20060216780-A1	09-28-2006	Wainwright et al.	
	A3*	US-20060183181-A1	08-17-2006	Wainwright et al.	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	B1	JP-61093958	05-12-1986	Daicel Chem	Abstract only in English	x
	B2	GB-A-2080524	02-03-1982	Mallinckrodt, Inc.		
	B3	WO-83/02123	06-23-1983	Soderhall		
	B4	WO-99/19355	04-22-1999	Jordan et al.		
	B5	WO-05/10207	02-03-2005	Wainwright et al.		
	B6	WO-06/76617 A3	07-20-2006	Wainwright et al.		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \* CITE NO.: Those application(s) which are marked with an single asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

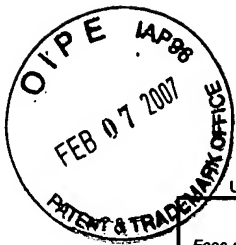
**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author ( in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C1	Coates, D.A., "Enhancement of the Sensitivity of the Limulus Assay for the Detection of Gram Negative Bacteria," (1977) Journal of Applied Bacteriology 42: 445-449.	
	C2	Inada et al., "A Silkworm Larvae Plasma Test for Detecting Peptidoglycan in Cerebrospinal Fluid is Useful for the Diagnosis of Bacterial Meningitis," (2003) Microbiology and Immunology, 47:(10): 701-707.	
	C3	Janda et al., "A Colorimetric Estimation of Lipopolysaccharides," (1970) Febs Letters 16: (4): 343-354.	
	C4	Maeda et al., "Chromogenic Assay Method of Lipopolysaccharide (LPS) for Evaluating Bacterial Standing Crop in Seawater," (1979) Journal of Applied Bacteriology 47: 175-182.	
	C5	Sigma Chemical Company E-Toxate Technical Bulletin (2000) No. 210: 1-4.	
	C6	Wiegel et al., "Determination of the Gram Type Using the Reaction Between Polymyxin B and Lipopolysaccharides of the Outer Cell Wall of Whole Bacteria," Journal of General Microbiology (1982) 28: 2261-2270.	
	C7	Charles River Laboratories, "LAL Products and Services" (2001).	
	C8	Prior, Richard B. Ed., (1990) "Clinical Applications of the Limulus Amebocyte Lysate Test" CRC Press, pp. 28-34.	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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PTO/SB/17 (07-06)  
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE  
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<b>Effective on 12/08/2004.</b> <b>Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).</b>		<b>Complete if Known</b>	
<b>FEE TRANSMITTAL</b> <b>For FY 2005</b>		Application Number	10/803,177
		Filing Date	March 17, 2004
		First Named Inventor	Norman R. Wainwright
		Examiner Name	N. A. Bowers
		Art Unit	1744
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27		Attorney Docket No.	CHR-004
<b>TOTAL AMOUNT OF PAYMENT</b>	<b>(\$)</b> 300.00		

**METHOD OF PAYMENT (check all that apply)**

☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): \_\_\_\_\_

☒ Deposit Account Deposit Account Number: 07-1700 Deposit Account Name: Goodwin Procter LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

☒ Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

**FEE CALCULATION****1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

**2. EXCESS CLAIM FEES**

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

<u>Total Claims</u>	<u>Extra Claims</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>	<u>Multiple Dependent Claims</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>
- = x =						
HP = highest number of total claims paid for, if greater than 20.						
<u>Indep. Claims</u>	<u>Extra Claims</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>			
- = x =						
HP = highest number of independent claims paid for, if greater than 3.						

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
- 100 =	/50	(round up to a whole number) x	=	

**4. OTHER FEE(S)**

	Fees Paid (\$)
Non-English Specification, \$130 fee (no small entity discount)	
Other (e.g., late filing surcharge):	
Petition for Extension of Time Under 37 CFR 1.136(a)	120.00
1806 Submission of an Information Disclosure Statement	180.00

**SUBMITTED BY**

Signature	<u>Robert D. Morin</u> <u>Reg No. 58,312</u>	Registration No. (Attorney/Agent)	38,678	Telephone	(617) 570-1299
Name (Print/Type)	Duncan A. Greenhalgh	Date	February 5, 2007		

PTO/SB/92 (09-06)  
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Application No. (if known): 10/803,177

Attorney Docket No.: CHR-004

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on February 5, 2007  
Date

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 Petition for Extension of Time Under 37 CFR 1.136(a) (1 page)  
 Amendment and Response to Office Action (11 pages)  
 Supplemental Information Disclosure Statement (2 pages)  
 Form PTO/SB/08 (1 page) with copies of citations B1-B6 and C1-C8  
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